

110TH CONGRESS  
1ST SESSION

# H. R. 1391

To accelerate efforts to develop vaccines for diseases primarily affecting developing countries, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 7, 2007

Mr. VISCLOSKY (for himself, Mr. RANGEL, Mr. KING of New York, Mr. McGOVERN, Ms. CARSON, and Mr. McNULTY) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Foreign Affairs and Financial Services, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To accelerate efforts to develop vaccines for diseases primarily affecting developing countries, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

### 3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Vaccines for the Fu-  
5 ture Act of 2007”.

### 6 **SEC. 2. DEFINITIONS.**

7 In this Act:

1           (1) AIDS.—The term “AIDS” has the meaning  
2           given the term in section 104A(g) of the Foreign As-  
3           sistance Act of 1961 (22 U.S.C. 2151b–2).

4           (2) APPROPRIATE CONGRESSIONAL COMMIT-  
5           TEES.—The term “appropriate congressional com-  
6           mittees” means the Committee on Appropriations  
7           and the Committee on Foreign Relations of the Sen-  
8           ate and the Committee on Appropriations and the  
9           Committee on Foreign Affairs of the House of Rep-  
10          resentatives.

11          (3) DEVELOPING COUNTRY.—The term “devel-  
12          oping country” means a country that the World  
13          Bank determines to be a country with a lower mid-  
14          dle income or less.

15          (4) HIV/AIDS.—The term “HIV/AIDS” has  
16          the meaning given the term in section 104A(g) of  
17          the Foreign Assistance Act of 1961 (22 U.S.C.  
18          2151b–2).

19          (5) GAVI ALLIANCE.—The term “GAVI Alli-  
20          ance” means the public-private partnership launched  
21          in 2000 for the purpose of saving the lives of chil-  
22          dren and protecting the health of all people through  
23          the widespread use of vaccines.

24          (6) NEGLECTED DISEASE.—The term “ne-  
25          glected disease” means—

- 1 (A) HIV/AIDS;
- 2 (B) malaria;
- 3 (C) tuberculosis; or
- 4 (D) any infectious disease that, according
- 5 to the World Health Organization, afflicts over
- 6 1,000,000 people and causes more than
- 7 250,000 deaths each year in developing coun-
- 8 tries.

9 (7) WORLD BANK.—The term “World Bank”  
10 means the International Bank for Reconstruction  
11 and Development.

12 **SEC. 3. FINDINGS.**

13 Congress makes the following findings:

14 (1) Immunization is an inexpensive and effec-  
15 tive public health intervention that has had a pro-  
16 found life-saving impact around the world.

17 (2) During the 20th century, global immuniza-  
18 tion efforts have successfully led to the eradication  
19 of smallpox and the elimination of polio from the  
20 Western Hemisphere, Europe, and most of Asia.  
21 Vaccines for diseases such as measles and tetanus  
22 have dramatically reduced childhood mortality world-  
23 wide, and vaccines for diseases such as influenza,  
24 pneumonia, and hepatitis help prevent sickness and  
25 death of adults as well as children.

1           (3) According to the World Health Organiza-  
2           tion, combined, AIDS, tuberculosis, and malaria kill  
3           more than 5,000,000 people a year, most of whom  
4           are in the developing world, yet there are no vac-  
5           cines for these diseases.

6           (4) Other, less well-known neglected diseases,  
7           such as pneumococcal disease, lymphatic filariasis,  
8           leptospirosis, leprosy, and onchocerciasis, result in  
9           severe health consequences for individuals afflicted  
10          with them, such as anemia, blindness, malnutrition  
11          and impaired childhood growth and development. In  
12          addition, these diseases result in lost productivity in  
13          developing countries costing in the billions of dollars.

14          (5) Infants, children, and adolescents are  
15          among the populations hardest hit by AIDS, ma-  
16          laria, and many other neglected diseases. Nearly  
17          11,000,000 children under age 5 die each year due  
18          to these diseases, primarily in developing countries.  
19          Existing and future vaccines that target children  
20          could prevent more than 2,500,000 of these illnesses  
21          and deaths.

22          (6) The devastating impact of neglected dis-  
23          eases in developing countries threatens the political  
24          and economic stability of these countries and con-

1       stitutes a threat to United States economic and se-  
2       curity interests.

3           (7) Of more than \$100,000,000,000 spent on  
4       health research and development across the world,  
5       only \$6,000,000,000 is spent each year on diseases  
6       that are specific to developing countries, most of  
7       which is from public and philanthropic sources.

8           (8) Despite the devastating impact these and  
9       other diseases have on developing countries, it is es-  
10      timated that only 10 percent of the world's research  
11      and development on health is targeted on diseases  
12      affecting 90 percent of the world's population.

13          (9) Because the developing country market is  
14      small and unpredictable, there is an insufficient pri-  
15      vate sector investment in research for vaccines for  
16      neglected diseases that disproportionately affect pop-  
17      ulations in developing countries.

18          (10) Creating a broad range of economic incen-  
19      tives to increase private sector research on neglected  
20      diseases is critical to the development of vaccines for  
21      neglected diseases.

22          (11) In recognition of the need for more eco-  
23      nomic incentives to encourage private sector invest-  
24      ment in vaccines for neglected diseases, an inter-  
25      national group of health, technical, and economic ex-

1       perts has developed a framework for an advance  
2       market commitment pilot program for pneumococcal  
3       vaccines. Pneumococcal disease, a cause of pneu-  
4       monia and meningitis, kills 1,600,000 people every  
5       year, an estimated 1,000,000 of whom are children  
6       under age 5. This pilot program will seek to stimu-  
7       late investments to develop and produce pneumo-  
8       coccal vaccines that could prevent between 500,000  
9       and 700,000 deaths by the year 2020.

10           (12) On February 9, 2007, 5 countries, Britain,  
11       Canada, Italy, Norway, and Russia, together with  
12       the Bill and Melinda Gates Foundation, pledged,  
13       under a plan called an Advance Market Commit-  
14       ment, to purchase pneumococcal vaccines now under  
15       development. Together, these countries and the Bill  
16       and Melinda Gates Foundation have committed  
17       \$1,500,000,000 for this program. Experts believe  
18       that this initiative could accelerate by a decade the  
19       widespread use of such a vaccine in the developing  
20       world and could prevent the deaths of an estimated  
21       5,400,000 children by 2030.

22       **SEC. 4. SENSE OF CONGRESS ON SUPPORT FOR NE-**  
23       **GLECTED DISEASES.**

24       It is the sense of Congress that—

1           (1) the President should continue to encourage  
2           efforts to support the Global HIV Vaccine Enter-  
3           prise, a virtual consortium of scientists and organi-  
4           zations committed to accelerating the development of  
5           an effective HIV vaccine;

6           (2) the United States should work with the  
7           Global Fund to Fight AIDS, Tuberculosis and Ma-  
8           laria, the Joint United Nations Programme on HIV/  
9           AIDS (“UNAIDS”), the World Health Organiza-  
10          tion, the International AIDS Vaccine Initiative, the  
11          GAVI Alliance, and the World Bank to ensure that  
12          all countries heavily affected by the HIV/AIDS pan-  
13          demic have national AIDS vaccine plans;

14          (3) the United States should support and en-  
15          courage the carrying out of the agreements of the  
16          Group of 8 made at the 2005 Summit at Gleneagles,  
17          Scotland, to increase direct investment and create  
18          market incentives, including through public-private  
19          partnerships and advance market commitments, to  
20          complement public research in the development of  
21          vaccines, microbicides, and drugs for HIV/AIDS,  
22          malaria, tuberculosis, and other neglected diseases;

23          (4) the United States should support the devel-  
24          opment of effective vaccines for infants, children,  
25          and adolescents as early as is medically and ethically

1 appropriate, in order to avoid significant delays in  
2 the availability of pediatric vaccines at the cost of  
3 thousands of lives;

4 (5) the United States should continue sup-  
5 porting the work of the GAVI Alliance and the Glob-  
6 al Fund for Children's Vaccines as appropriate and  
7 effective vehicles to purchase and distribute vaccines  
8 for neglected diseases at an affordable price once  
9 such vaccines are discovered in order to distribute  
10 them to the developing world;

11 (6) the United States should work with others  
12 in the international community to address the mul-  
13 tiple obstacles to the development of vaccines for ne-  
14 glected diseases including scientific barriers, insuffi-  
15 cient economic incentives, protracted regulatory pro-  
16 cedures, lack of delivery systems for products once  
17 developed, liability risks, and intellectual property  
18 rights; and

19 (7) the United States should contribute to the  
20 pilot Advance Market Commitment for pneumococcal  
21 vaccines launched in Rome on February 9, 2007,  
22 which could prevent some 500,000 to 700,000 child  
23 deaths by the year 2020 and an estimated 5,400,000  
24 child deaths by 2030.



1 **SEC. 5. PUBLIC-PRIVATE PARTNERSHIPS.**

2 (a) FINDINGS.—Congress makes the following find-  
3 ings:

4 (1) Partnerships between governments and the  
5 private sector (including foundations, universities,  
6 corporations, community-based organizations, and  
7 other nongovernmental organizations) are playing a  
8 critical role in the area of global health, particularly  
9 in the fight against neglected diseases, including  
10 HIV/AIDS, tuberculosis, and malaria.

11 (2) These public-private partnerships improve  
12 the delivery of health services in developing countries  
13 and accelerate research and development of vaccines  
14 and other preventive medical technologies essential  
15 to combating infectious diseases that disproportion-  
16 ately kill people in developing countries.

17 (3) These public-private partnerships maximize  
18 the unique capabilities of each sector while com-  
19 bining financial and other resources, scientific  
20 knowledge, and expertise toward common goals  
21 which cannot be achieved by either sector alone.

22 (4) Public-private partnerships such as the  
23 International AIDS Vaccine Initiative, PATH's Ma-  
24 laria Vaccine Initiative, and the Global TB Drug  
25 Facility are playing cutting edge roles in the efforts  
26 to develop vaccines for these diseases.

1           (5) Public-private partnerships serve as incen-  
2           tives to the research and development of vaccines for  
3           neglected diseases by providing biotechnology compa-  
4           nies, which often have no experience in developing  
5           countries, with technical assistance and on the  
6           ground support for clinical trials of the vaccine  
7           through the various stages of development.

8           (6) Sustaining existing public-private partner-  
9           ships and building new ones where needed are essen-  
10          tial to the success of the efforts by the United States  
11          and others in the international community to find a  
12          cure for these and other neglected diseases.

13          (b) SENSE OF CONGRESS.—It is the sense of Con-  
14          gress that—

15               (1) the sustainment and promotion of public-  
16               private partnerships must be a central element of  
17               the strategy pursued by the United States to create  
18               effective incentives for the development of vaccines  
19               and other preventive medical technologies for ne-  
20               glected diseases debilitating the developing world;  
21               and

22               (2) the United States Government should take  
23               steps to address the obstacles to the development of  
24               these technologies by increasing investment in re-

1 search and development and establishing market and  
2 other incentives.

3 **SEC. 6. COMPREHENSIVE STRATEGY FOR ACCELERATING**  
4 **THE DEVELOPMENT OF VACCINES FOR NE-**  
5 **GLECTED DISEASES.**

6 (a) REQUIREMENT FOR STRATEGY.—The President  
7 shall establish a comprehensive strategy to accelerate ef-  
8 forts to develop vaccines and microbicides for neglected  
9 diseases such as HIV/AIDS, malaria, and tuberculosis.  
10 Such strategy shall—

11 (1) expand public-private partnerships and seek  
12 to leverage resources from other countries and the  
13 private sector;

14 (2) include the negotiation of advance market  
15 commitments and other initiatives to create eco-  
16 nomic incentives for the research, development, and  
17 manufacturing of vaccines and microbicides for HIV/  
18 AIDS, tuberculosis, malaria, and other neglected  
19 diseases;

20 (3) address intellectual property issues sur-  
21 rounding the development of vaccines and  
22 microbicides for neglected diseases;

23 (4) maximize United States capabilities to sup-  
24 port clinical trials of vaccines and microbicides in  
25 developing countries;

1           (5) address the issue of regulatory approval of  
2           such vaccines and microbicides, whether through the  
3           Commissioner of the Food and Drug Administration,  
4           or the World Health Organization, or another entity;  
5           and

6           (6) expand the purchase and delivery of existing  
7           vaccines.

8           (b) REPORT.—Not later than 180 days after the date  
9           of enactment of this Act, the President shall submit to  
10          the appropriate congressional committees a report setting  
11          forth the strategy described in subsection (a) and the steps  
12          to implement such strategy.

13       **SEC. 7. ADVANCE MARKET COMMITMENTS.**

14          (a) PURPOSE.—The purpose of this section is to im-  
15          prove global health by creating a competitive market for  
16          future vaccines through advance market commitments.

17          (b) AUTHORITY TO NEGOTIATE.—

18               (1) IN GENERAL.—The Secretary of the Treas-  
19               ury shall enter into negotiations with the appro-  
20               priate officials of the World Bank, the International  
21               Development Association, and the GAVI Alliance,  
22               the member nations of such entities, and other inter-  
23               ested parties for the purpose of establishing advance  
24               market commitments to purchase vaccines and  
25               microbicides to combat neglected diseases.

1           (2) REPORT.—Not later than 180 days after  
2       the date of the enactment of this Act, the Secretary  
3       shall submit to the appropriate congressional com-  
4       mittees a report on the status of the negotiations to  
5       create advance market commitments under this sec-  
6       tion. This report may be submitted as part of the re-  
7       port submitted under section 6(b).

8       (c) REQUIREMENTS.—The Secretary of the Treasury  
9       shall work with the entities referred to in subsection (b)  
10      to ensure that there is an international framework for the  
11      establishment and implementation of advance market  
12      commitments and that such commitments include—

13           (1) legally binding contracts for product pur-  
14      chase that include a fair market price for a guaran-  
15      teed number of treatments to ensure that the mar-  
16      ket incentive is sufficient;

17           (2) clearly defined and transparent rules of  
18      competition for qualified developers and suppliers of  
19      the product;

20           (3) clearly defined requirements for eligible vac-  
21      cines to ensure that they are safe and effective;

22           (4) dispute settlement mechanisms; and

23           (5) sufficient flexibility to enable the contracts  
24      to be adjusted in accord with new information re-  
25      lated to projected market size and other factors

1 while still maintaining the purchase commitment at  
2 a fair price.

3 (d) AUTHORIZATION OF APPROPRIATIONS.—

4 (1) IN GENERAL.—There are authorized to be  
5 appropriated such sums as may be necessary for  
6 each of fiscal years 2009 through 2014 to fund an  
7 advance market commitment pilot program for pneu-  
8 mococcal vaccines.

9 (2) AVAILABILITY.—Amounts appropriated pur-  
10 suant to this subsection shall remain available until  
11 expended without fiscal year limitation.

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